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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/435,770	11/08/99	YAMAMOTO T	YAMAMOTO=16A

EXAMINER	
FRONDA,C	
ART UNIT	PAPER NUMBER
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DATE MAILED: 07/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/435,770	Yamamoto et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-51 is/are pending in the application.

4a) Of the above, claim(s) 14-51 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-13 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/392,253.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 5
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. In the **RESPONSE TO RESTRICTION REQUIREMENT** dated 20, 2001 (paper no. 17), Applicants have elected Group I, claims 1-13, with traverse.

Applicant's election with traverse of Group I, claims 1-13, is acknowledged. The traversal is on the ground(s) that there is no serious burden to examine all the inventions of Groups I-V. This is not found persuasive because the non-reducing saccharide-forming enzyme of Group I, the DNA encoding a non-reducing saccharide-forming enzyme of Group II, the a trehalose-releasing enzyme of Group III, and the DNA encoding a trehalose-releasing enzyme of Group IV are independent chemical entities and require different literature searches. Furthermore, the process of Group V which uses the product of Group I can be practiced with another materially different product such as organic catalysts and organic chemicals used in the chemical synthesis of a saccharide. A search of all the inventions of Groups I-V in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-13 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the meaning of the phrase "medium temperature range" is not known and has not been defined in the specification. Claims 2-13 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

In claim 3, the meaning of the phrase "an acid pH range" is not known and has not been defined in the specification.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated non-reducing saccharide-forming enzyme obtainable from *Arthrobacter* sp. S34 (FERM BP-6450) comprising an amino acid sequence as set forth in SEQ ID NO:1; does not reasonably provide enablement for any non-reducing saccharide-forming enzyme obtainable from any biological source or encoded by an DNA, any non-reducing saccharide-forming enzyme comprising an amino acid sequence having at least 57% homology to the amino acid sequence of SEQ ID NO:1, or any non-reducing saccharide-forming enzyme having an amino acid sequence comprising a part or whole of the amino acid sequence of SEQ ID NOs:1-6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompasses any non-reducing saccharide-forming enzyme obtainable from any biological source, any non-reducing saccharide-forming enzyme comprising an amino acid sequence having at least 57% homology to the amino acid sequence of SEQ ID NO:1, or any non-reducing saccharide-forming enzyme having an amino acid sequence comprising a part of the amino acid sequence of SEQ ID Nos:1-6. The specification provides guidance and examples for isolating a non-reducing saccharide-forming enzyme from *Arthrobacter* sp. S34 (FERM BP-6450) comprising an amino acid sequence as set forth in SEQ ID NO:1. While molecular biological techniques and genetic manipulation to make the claimed polynucleotides are known in the prior art and the skill of the artisan are well developed, knowledge regarding the amino acid residues to change in SEQ ID NO:1, i.e. delete, insert, substitute, and combinations thereof, to make a polypeptide having 57% identity to of SEQ ID NO: 1 and still retain enzyme activity or the specific biological source which has a non-reducing saccharide-forming enzyme is lacking. Thus, searching for amino acid residues to change in

SEQ ID NO:1 or the biological source of the claimed enzyme is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to determine what specific amino acid residues to change in SEQ ID NO: 1 to make a polypeptide having 57% identity to SEQ ID NO: 1 and still retain enzyme activity or what biological source has a non-reducing saccharide-forming enzyme is enormous. Such experimentation entails selecting specific amino acid residues to modify in SEQ ID NO: 1, making a DNA encoding the mutated amino acid sequence, recombinantly expressing the mutants, and screening for mutants that have 57% identity to the amino acid sequence of SEQ ID NO: 1 and still retain enzyme activity. Alternatively, experimentation entails screening a vast number of organisms for an organism having a non-reducing saccharide-forming enzyme, isolating the enzyme from the selected biological source, obtaining the amino acid sequence and DNA sequence of the isolated enzyme, and determining if the isolated enzyme has 57% identity to SEQ ID NO: 1.

Since routine experimentation in the art does not include making and screening for a vast number of mutants having 57% identity to SEQ ID NO: 1 or having part of SEQ ID NOs:1-6 and still retain enzyme activity or screening for a biological source out of a vast number of organisms for an organism having a non-reducing saccharide-forming enzyme where the expectation of obtaining a desired polypeptide having 57% identity to SEQ ID NO: 1 or having part of SEQ ID Nos:1-6 and still retain enzyme activity is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific amino acid residues to mutate in SEQ ID NO: 1 or the biological source of the claimed enzyme. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 2-13 which depend from claims 1 are also rejected because they do not correct the defect of claim 1.

7. Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The microorganism *Arthrobacter* sp. S34 (FERM BP-6450) is required to practice the claimed invention. The microorganism must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. It is not apparent if the *Arthrobacter* sp. S34 (FERM BP-6450) or source materials to make *Arthrobacter* sp. S34 (FERM BP-6450) are both known and readily available to the public. Therefore, a deposit at a recognized depository must be made for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction

released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

(1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;

(3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(4) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubota et al.

Kubota et al. teach a non-reducing saccharide-forming enzyme which is obtainable from *Rhizobium* sp. M11 (a microorganism species of the genus *Arthrobacter*) and has an optimum temperature of over 40°C but below 60°C, and DNA encoding said non-reducing saccharide-forming enzyme (see entire publication). The non-reducing saccharide-forming enzyme taught by Kubota et al. has an amino acid sequence comprising part of the claimed amino acid sequences set forth as SEQ ID Nos: 1-6 (see **Alignment Nos. 1-6)**

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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